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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,600	03/24/2004	David Nordman	L-8XC1	7238

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,600	Applicant(s) NORDMAN ET AL.	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment filed 16 November 2007 is acknowledged and has been entered. Claims 22-31 are newly added. Claims 1-21 have been cancelled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 22-26, the interrelationships of the components and steps of the method are not clear, e.g.: the interrelationships between complexes and reaction are not clear; the interrelationships of the detection reagent to the complexes and reaction, or to the measuring, are not clear; and, it is not clear how one evaluates or takes into consideration the value. The recitation of "use" is not a valid method step. In these claims it is not clear what applicant intends as within the metes and bounds of the invention because it is not clear what is encompassed by "physical, chemical, and/or antigenic properties in common". In these claims, "the" presence or absence, formation, reaction, lowest, and results lack antecedent basis.

In claim 26, the interrelationships of a detection molecule to the detection reagent, or to the complexes and reaction, or to the measuring, are not clear. It is also not clear what is being further limited as the negative control value is already determined from a reaction (or lack thereof) between capture reagents and the detection reagent. In this claim, "the" reaction lacks antecedent basis.

In claims 27-31, "the" presence or absence, reactivity, sample-specific, and least lack antecedent basis. In these claims it is not clear what applicant intends as within the metes and bounds of the invention because it is not clear what is encompassed by "physical, chemical, and/or antigenic properties in common".

In claim 31, the interrelationships of a detection molecule to measuring the reactivity are not clear. It is also not clear what is being further limited as the negative control is already determined from measuring reactivity (or lack thereof) between capture reagents and sample. In this claim, "the" control value, reaction, and solid support lack antecedent basis.

Applicant's arguments filed 16 November 2007 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-31 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Douillard et al. (Meth. Enz. 92: 168, 1983) for reasons of record in the prior rejection of the similar subject matter of claims 9-13.

Claims 22-31 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Hoffman et al. (US 5,599,543) for reasons of record in the prior rejection of the similar subject matter of claims 9-13.

Applicant's arguments filed 16 November 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's invention as is now claimed wherein capture reagents have "physical, chemical, and/or antigenic properties in common" does not exclude the soluble protein antigens taught by the reference of Douillard et al. or the peptide circumsporozoite protein repeat regions of different parasite species taught by the reference of Hoffman et al. in light of applicant's disclosure that merely solubility or molecular weight or being a homologue from a different species may be common properties shared by the controls and (relevant) capture reagent(s) (see e.g. specification page 4). Notwithstanding applicant's arguments to the contrary, those reactants serving as the negative controls are irrelevant capture reagents with regard to forming complexes with the analyte.

Claims 22-31 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Geysen et al. (Proc. Natl. Acad. Sci. USA 81: 3998, 1984).

Geysen et al. teach determination of positive responses for antibody analytes in serum samples with enzyme-linked immunosorbent assays. Negative controls include antigens of similar structure (see e.g. Figs. 2 or 3), or antigens from a homologue from a different species (see e.g. Table 1), and/or a set of unrelated antibodies (see e.g. Fig. 2). Positives are those wells with values above value(s) in the well(s) chosen as the negative (see e.g. Figs. 2 or 3, and pages 4000-4001). Although the reference inherently uses subtraction or division in determining that

levels were elevated above the background, the mental process steps of subtraction for data manipulation, involving no active process steps, have not been accorded any patentable weight.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.


The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JLG/

James L. Grun, Ph.D.
January 30, 2008


LONG V. LE 02/01/08
SUPERVISORY PATENT EXAMINER
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